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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/237,183	01/26/1999	NORDINE CHEIKH	04983.0015.U	9529

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ARNOLD & PORTER
IP DOCKETING DEPARTMENT; RM 1126(b)
555 12TH STREET, N.W.
WASHINGTON, DC 20004-1206

EXAMINER

MARSCHER, ARDIN H

ART UNIT	PAPER NUMBER
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1631

DATE MAILED: 07/16/2002

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Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.
09/237,183

Applicant(s)
Cheikh et al.

Examiner
Ardin Marschel

Art Unit
1631

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on Apr 29, 2002.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1, 2, and 7-17 is/are pending in the application.
- 4a) Of the above, claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1, 2, and 7-17 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☒ Claims 1, 2, and 7-17 are subject to restriction and/or election requirement.

Application Papers

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☐ All b) ☐ Some* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
*See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).
a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892) 4) ☐ Interview Summary (PTO-413) Paper No(s). _____
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948) 5) ☐ Notice of Informal Patent Application (PTO-152)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449) 132 sheets 6) ☐ Other:

Applicants' arguments, filed 4/29/02, have been fully considered but they are not deemed to be persuasive. Rejections and/or objections not reiterated from previous office actions are hereby withdrawn. The following rejections and/or objections are either reiterated or newly applied. They constitute the complete set presently being applied to the instant application.

Applicants have requested clarification of the restriction requirement as noted on page 1 of the previous office action, mailed 1/29/02, regarding claims 1, 2, and 7-17. It is assumed for this clarification that applicants are questioning the indication in item # 8 on page 1 of said office action, mailed 1/29/02. This indication in said item # 8 is merely to be informative to applicants as to the maintaining of the requirement for sequence election requirement as being limited to 10 sequences as set forth in the previous office action, mailed 10/4/00, and elected by applicants in Paper No. 7, filed 11/3/00. It is noted that instant claim 1 clearly is broader in scope than the 10 elected sequences. Thus, this item # 8 indication reaffirms that the examination of instant claim 1 especially extends only over said 10 elected sequences and not others.

LACK OF UTILITY REJECTION

The pending claims have been reviewed in light of the Utility Examination Guidelines and Guidelines for Examination of Patent Applications under 35 U.S.C. 112, first paragraph,

"Written Description" Requirement, Federal Register, Vol. 66, No. 4, pages 1092-1111, Friday, January 5, 2001.

The examiner is using the following definitions in evaluating the claims for utility.

"Specific" - A utility that is *specific* to the subject matter claimed. This contrasts with a *general* utility that would be applicable to the broad class of the invention.

"Substantial" - A utility that defines a "real world" use. Utilities that require or constitute carrying out further research to identify or reasonably confirm a "real world" context of use are not substantial utilities.

"Credible" - Credibility is assessed from the perspective of one of ordinary skill in the art in view of the disclosure and any other evidence of record that is probative of the applicant's assertions. That is, the assertion is an inherently unbelievable undertaking or involves implausible scientific principles.

"Well-established" - a specific, substantial, and credible utility which is well known, immediately apparent, or implied by the specification's disclosure of the properties of a material, alone or taken with the knowledge of one skilled in the art.

35 U.S.C. § 101 reads as follows:

"Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter or any new and useful improvement thereof, may obtain a patent

therefore, subject to the conditions and requirements of this title".

Claims 1, 2, and 7-17 are rejected under 35 U.S.C. § 101 because the claimed invention lacks patentable utility due to its not being supported by either specific and/or substantial utility or a well established utility.

This rejection is maintained and reiterated from the previous office action, mailed 1/29/02. Applicants argue firstly that two cited articles indicate that sequence similarity is routinely utilized as a predictor of function. In response neither of these articles indicate that such sequence similarity is predictable or even reasonably reliable or routine for function prediction. Thus, this argument of applicants is an allegation without factual support and therefore non-persuasive, especially in the face of factual support as set forth in the previous office action, mailed 1/29/02. In fact, it is fully expected that research efforts directed at the sequencing of large nucleic acid sequences would primarily, if not fully, occupy the available time during such research projects such that reliably performing further research into function, for example, would take second place at best.

LACK OF ENABLEMENT REJECTION

Claims 1, 2, and 7-17 are also rejected under 35 U.S.C. § 112, first paragraph. Specifically, since the claimed invention

is not supported by either a specific and substantial asserted utility or a well established utility for the reasons set forth above, one skilled in the art would not know how to use the claimed invention. This rejection is reiterated and maintained from the previous office action, mailed 1/29/02. The arguments regarding this rejection have already been responded to regarding the above lack of utility rejection as being equally non-persuasive for the same reasons as given above.

LACK OF WRITTEN DESCRIPTION REJECTION

Claims 1, 2, and 7-17 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

This lack of written description rejection is maintained and reiterated from the previous office action, mailed 1/29/02. Applicants argue that adequate written description of a genus is set forth by recitation of structural features in common thus permitting a capability of distinguishing members of the claimed genus from non-members. In response this capability or not is not the issue as the basis for this rejection. The issue is a lack of sequence information in written form for the encoding of full enzymes as cited in the claims. It is noted that fragments

of such enzymes do have written description in the SEQ ID NO. sequence but not the sequence beyond the actual SEQ ID NO. sequences. It is immaterial for this rejection what "can" be obtained by experimentation. The invention as directed to the full enzyme coding sequences lacks written description and still supports this rejection. The specification at pages 75-77 84, and 85 are cited as disclosing other information such as promoters etc. Consideration of said pages has failed to reveal any sequence information regarding completing the enzyme sequence written description and therefore is non-persuasive regarding this rejection.

The disclosure is objected to because it contains an embedded hyperlink and/or other form or browser-executable code. Applicants are required to delete the embedded hyperlink and/or other form of browser-executable code. See MPEP § 608.01. Such code is present in the specification at page 19, lines 10-17, and elsewhere. It is noted that applicants have reduced the code but, unfortunately not enough. An attempt to utilize the remaining hyperlinks by the Examiner's computer resulted in these hyperlinks still being usable and interpretable as such. Therefore, further deletion is required in order to satisfy this correction requirement. This objection is still maintained as applicants have not responded to the basis for this objection which is that the remaining hyperlinks in the specification still

remain fully functional as hyperlinks as noted above.

Applicants' allegation that they are not is contrary to the factual situation. Appropriate correction is required.

Enclosed with this office action are several PTO Forms 1449 which have been executed but inadvertently not mailed previously.

No claim is allowed.

THIS ACTION IS MADE FINAL. Applicants are reminded of the extension of time policy as set forth in 37 C.F.R. § 1.136(a).

A SHORTENED STATUTORY PERIOD FOR RESPONSE TO THIS FINAL ACTION IS SET TO EXPIRE THREE MONTHS FROM THE DATE OF THIS ACTION. IN THE EVENT A FIRST RESPONSE IS FILED WITHIN TWO MONTHS OF THE MAILING DATE OF THIS FINAL ACTION AND THE ADVISORY ACTION IS NOT MAILED UNTIL AFTER THE END OF THE THREE-MONTH SHORTENED STATUTORY PERIOD, THEN THE SHORTENED STATUTORY PERIOD WILL EXPIRE ON THE DATE THE ADVISORY ACTION IS MAILED, AND ANY EXTENSION FEE PURSUANT TO 37 C.F.R. § 1.136(a) WILL BE CALCULATED FROM THE MAILING DATE OF THE ADVISORY ACTION. IN NO EVENT WILL THE STATUTORY PERIOD FOR RESPONSE EXPIRE LATER THAN SIX MONTHS FROM THE DATE OF THIS FINAL ACTION.

This application contains sequence species in claim 1 drawn to an invention non-elected with traverse in Paper No. 7, filed 11/3/00. A complete response to the final rejection must include cancellation of non-elected claims or other appropriate action (37 C.F.R. § 1.144) M.P.E.P. § 821.01.

Papers related to this application may be submitted to Technical Center 1600 by facsimile transmission. Papers should be faxed to Technical Center 1600 via the PTO Fax Center located in Crystal Mall 1. The faxing of such papers must conform with the notices published in the Official Gazette, 1096 OG 30 (November 15, 1988), 1156 OG 61 (November 16, 1993), and 1157 OG 94 (December 28, 1993) (See 37 CFR § 1.6(d)). The CM1 Fax Center number is either (703)308-4242 or (703)305-3014.

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Any inquiry concerning this communication or earlier communications from the examiner should be directed to Ardin Marschel, Ph.D., whose telephone number is (703)308-3894. The examiner can normally be reached on Monday-Friday from 8 A.M. to 4 P.M.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Woodward, Ph.D., can be reached on (703)308-4028.

Any inquiry of a general nature or relating to the status of this application should be directed to Patent Analyst, Tina Plunkett, whose telephone number is (703)305-3524 or to the Technical Center receptionist whose telephone number is (703) 308-0196.

July 12, 2002

Ardin H. Marschel
ARDIN H. MARSCHEL
PRIMARY EXAMINER